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(54) Expandable ring, cylinder or sleeve which can be made non-deformable.

(57) Expandable ring or cylinder (so-called "stent") for locally supporting or strengthtening a body vessel, particularly a blood vessel, and which is filled with curable material which cures when the stent is brought at the desired position in the vessel by means of a catheter or dotter - like device.

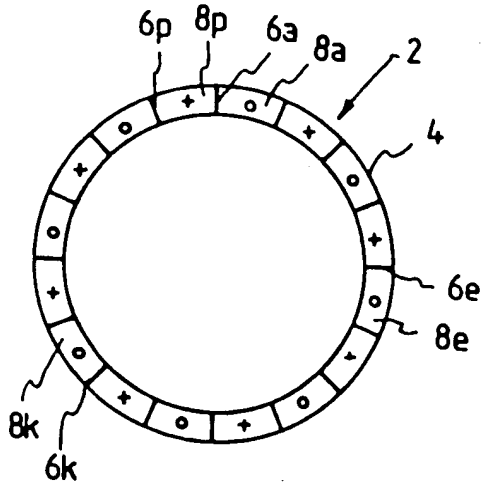

Fig. 1

EP 0 521 573 A2

The invention relates to an expandable ring or cylinder, particularly for locally supporting or strengthening a body vessel, comprising an expandable body being able to retain its expanded shape after its introduction at the desired location.

Such a device particularly with a cylinder shape and commonly called a "stent" is known from EP-A-0 428 479. This document proposes the use of a hollow body which is made up of a plastics having such properties that it can be elastically deformed when heating at a temperature about 75 °C. The body is placed around a heatable dotter balloon which is brought at the desired place whereafter the dotter balloon is heated and inflated so that the plastics material of the body softens and expands with the balloon; when then the heating is ended and the body cools off it is expected to retain its shape.

This known device has several drawbacks. The first one is that in the solid state the hollow body is rigid so that there is a real risk of damaging the vessels through which it has to pass so that the treatment can cause severe suffering to the patient. The second drawback is that there is a very limited source of materials from which the hollow body can be made: it must be soften when heated and become solid again after cooling-off while at the same time it must be compatible with the body environment as it remains in the body. Of course another severe drawback is the fact that the body must be heated to a temperature which lies considerably above the body temperature of the patient. Furthermore the very nature of the, rigid, material as used limits the extent to which it can be expanded.

The invention aims to obviate these drawbacks. According to the invention this is achieved in that said body is hollow and contains a curable plastics material which can cure after the positioning and thus assures that the desired expanded shape is retained.

With the measures according to the invention is obtained that the body of the stent is very soft and pliable before the curing of the curable materials therein so that the introduction will not be much more difficult than the known "dotter" treatment: there will be no objectionable temperature rise. The final shape can be rigidly controlled and adapts itself easily to the vessel in which it is inserted. The device according to the invention can thus be used much more universally than the known device.

Preferably the hollow body is devided into at least two compartments which are separated from eachother by at least one partition which can be broken, the compartments each being filled with a first and a second substance respectively, the mixing together of which leads to a reaction resulting in curing of the produced mixture.

Preferably said partition has such a configuration that, when the diameter of the element is increased, a passage is opened between the compartments.

Further prefered embodiments are described in claims 4-13.

When the curing material is of the kind of which the curing starts a predetermined period after the mixing of its components the partition (s) can be broken outside the patient's body, thus before the treatment starts because the time, necessary for reaching the desired location, can be determined with a good approximation beforehand on the basis of a scan of the patient's body.

Further embodiments are discribed in claims 15-20.

The invention is explained with reference to the drawing, in which:

Figure 1 is a longitudinal section through a first embodiment of the invention, in the non-expanded state;

Figure 2 is a perspective view of this embodiment;

Figure 3 is a longitudinal section of this embodiment, in the expanded state;

Figure 4 is a longitudinal section through a second embodiment of the invention, in the non-expanded state;

Figure 5 is a perspective view of this embodiment;

Figure 6 is a longitudinal section of this embodiment, in the expanded state;

Figure 7 is a cross-section through a second embodiment according to the invention;

Figure 8 is a longitudinal section through a part of a blood vessel containing an expandable ring according to the invention, in the state prior to its expansion;

Figure 9 is a longitudinal section according to Figure 3, with the ring expanded and the inflatable balloon still present;

Figure 10 is a longitudinal section through the final blood vessel configuration.

Figure 11 shows schematically a sleeve-shaped device according to the invention.

Figures 12a-12d show several stages of the treatment of a body vessel having a constriction of considerable length.

Figure 13 shows another embodiment according to the invention.

In Figure 1 reference numeral 2 indicates an expandable supporting ring according to the invention, comprising a closed tubular element 4 which is divided by means of partitions 6a - 6p into a number of compartments 8a - 8p. Each of these compartments is filled with one of two chemical substances which differ from each other and on mixing undergo a reaction which leads to the cur-

ing of the resulting mixture. The compartments marked with a cross (+) are filled with the first substance, while the compartments marked with a dot (.) are filled with the second substance. It is possible to use, for example, an epoxy resin curing system in which the first substance is an epoxy resin, for example Shell's EPIKOTE® combined with a suitable amine curing agent; the reaction taking place between these substances leads already at body temperature to complete curing of the resulting mixture within a few minutes, so that the fitting can take place quickly and the patient suffers as little discomfort as possible. Another suitable combination is an unsaturated polyester as the first substance and benzoyl peroxide catalyst as the second substance. Use can also be made of a diisocyanate compound as the first substance and water or a water-containing solvent as the second substance. Even the use of the component parts of plaster of Paris (lime and water) is conceivable. For other suitable combinations referrence is made to "Handbook of Composites", George Lubin, published in 1982 by Van Nostrand Reinhold Company Inc.

When the diameter of such a ring, shown in perspective in Figure 2, is enlarged in a suitable manner from within this results in the situation shown in Figure 3, in which the respective partitions 6a..6p have all been broken through so that the substances present in the compartments 8a..8p are mixed together, with the result that the curing reaction then occurring leads to a non-deformable, solid ring which permanently retains the shape acquired.

Figure 4 shows a longitudinal section through a second embodiment according to the invention; this embodiment is shown in perspective in Figure 5 and expanded in Figure 6. The ring 10 is divided, by a circular partition 12 running parallel to the central axis 11, into two concentric compartments 14 and 16, of which the compartment 14 is filled with the first substance, and the compartment 16 is filled with the second substance. Figure 6 shows how on expansion of the ring 10 the partition 12 is broken through and the two substances quickly mix together over the entire periphery of the ring.

Figure 7 shows in cross-section an embodiment in which the ring 20 is divided into the two compartments 26 and 28 by a partition 24 running all the way round at right angles to the central axis 22. The whole works in a corresponding way to that which is described above.

Figure 8 shows the way in which a ring according to the invention can be used. The figure shows in cross-section a blood vessel 30 with a local constriction 32. The ring 34 is fitted by means of a suitable instrument at this point, and an inflatable balloon 38 is introduced into the hollow space 36 thereof, for example of the type used in the case of the so-called "dotter" treatment. As Figure 5 illustrates, the balloon is inflated, with the result that the ring 34 expands, thus removing the constriction 32. Within a few minutes of the breaking of the partition(s) in the ring the chemical reaction between the respective substances present in the compartments of the ring is completed and the ring 34 has permanently acquired the configuration shown in Figure 10. The balloon 38 can be withdrawn and the constriction of the vessel 32 is permanently mended.

Figure 11 shows the expandable element in the form of a sleeve-shaped configuration 40, comprising an outer wall 42, an inner wall 44, end walls 46 and 48, and a partition 50 which divides everything into two compartments 52 and 54. A blood vessel or organ can be supported over a greater distance with such an expandable element.

Figure 12a shows how a body vessel 60, particularly a blood vessel has, between the points 62a and 62b a number of constrictions 64 which considerable affect the flow of body fluid. By means of a body scan the distance between the location 62a and 62b is determined and then a device according to the invention is chosen with such a length that it covers said distance. Furthermore the free diameter d of the body vessel is also determined and a stent is chosen with such a diameter that, when it is brought into position and the dotter balloon is inflated it presses itself into the body vessel in such a way that after the curing of its components a smooth transition between the unrestricted part and the stand is obtained.

Figure 12b shows the dotter device 64 and the stent according to the invention, indicated with 66, around it and fixed to the dotter device with the surgical tread 68. The stent 66 is divided into two compartments 70a, 70b separated by the partition 72. This partition can be broken before the dotter - like device is inserted into the body vessel or can be of the kind with breaks when the dotter device 64 is infated. The inflation of the dotter - like device results into the situation according to figure 12c: the stent 66 is pressed into the wall of the vessel 60 to such an extend that there are smooth transitions 74 between the wall of the unrestricted parts and the inner diameter of the stent 66.

When, after curing of the component materials in the stent 66 the dotter device is retracted the stent 66 remains in the body vessel 60 as shown in figure 12d.

Finally figure 13 shows the use of a stent 80 according to the invention which has only one compartment 82 which is filled with mixture of materials of which the curing starts when it is irradiated with radiation of a suitable wave length, particularly UV light. In the manner as described

above this stent is fixed by means of the surgical threads 68 to the dotter - like device 66. Together with the dotter - like device 66 a light conducting glas fiber 84 with at its one end a small lens 86 is inserted into the body; when the whole has reached the desired position the other end 88 is irradiated with ultra violet light from a suitable source 90 via a schematically shown focussing system 92. In this way a considerable amount of UV energy can be transmitted to the desired position, resulting into a rapid curing of the curable material.

It is clear that countless variants are possible within the scope of the invention. For example, it is conceivable to fill the respective compartments with more than two different substances, while many variants are also possible in shape, size and cross-section configuration.

Applications other than the medical application described are, of course, also possible.

Claims

1. Ring or cilinder, particularly for locally supporting or strenghtening a body vessel comprising a body able to maintain a desired shape after its positioning at the desired location, **characterised in that** said body is hollow and contains curable material which can cure after the positioning and thus assures that the desired shape is maintained.

2. Device according to claim 1, **characterised in that**, the hollow body is devided into at least two compartments which are separated from eachother by at least one partition which can be broken, the compartments each being filled with a first and a second substance respectively, the mixing together of which leads to a reaction resulting in curing of the produced mixture.

3. Device according to claim 2, **characterised in that** said partition has such a configuration that, when the diameter of the element is increased, a passage is opened between the compartments.

4. Device according to claim 3, **characterised in that** the partition runs concentrically with the outer limits of the element about its central axis.

5. Device according to claim 4, **characterised in that** the partition is parallel to the central axis.

6. Device according to claim 4, **characterised in that** the partition lies at right angles to the central axis.

7. Device according to claim 3, **characterised in that** the partition (s) runs or run radially.

8. Device according to claims 3 - 7, **characterised in that** the partition(s) is (are) made of material which tears when put under tension.

9. Device according to claims 7 - 8, **characterised by** a nymber of compartments distributed along its periphery and filled alternately with a first and a second substance, all this in such a way that when connections are made between them the reaction starts simultaneously over essentially the entire periphery.

10. Device according to claims 3 - 9, **characterised by** a weakened part in a partition.

11. Device according to claims 3 - 10, **characterised by** an opening in a partition which expands on stretching.

12. Device according to claims 3 - 11, **characterised by** a part which disintegrates after a predetermined period and thus clears an opening in a partition.

13. Device according to claims 2 - 12, **characterised in that** the curing material is of the kind of which the curing starts a predetermined period after the mixing of its components.

14. Device according to claim 1, **characterised by** means for introducing the curing material in said hollow body when same has been positioned at the desired location.

15. Device according to claims 1 - 14, **characterised in that** its shape makes it possible to hold it around an uninflated dotter - like device during the insertion thereof in a body vessel.

16. Device according to claim 15, **characterised in that** the body is spirally wound around the uninflated dotter device.

17. Device according to claims 15 - 16, **characterised in that** the body is fixed to the dotter - like device by means of threads which break when the dotter - like device is inflated.

18. Device according to claim 17, **characterised in that** the curable material is of the kind of which the curing is started or accelerated under the influence of radiation with a suitable wave length.

19. Device according to claim 18, **characterised in that** said radiation is UV light.

20. Device according to claim 18-19, **characterised by** a light conducting fiber for transmitting the radiation from an outside source to the curable material.

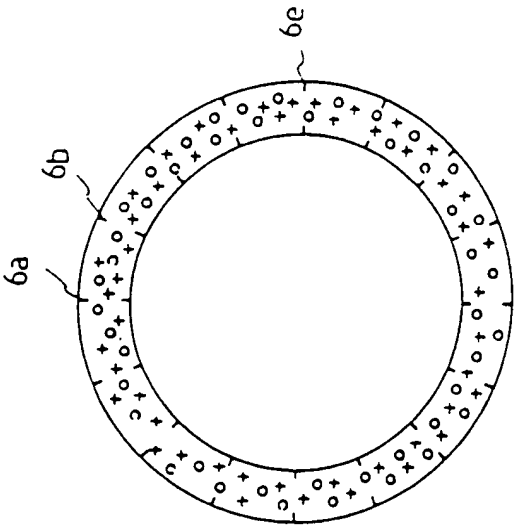

Fig. 3

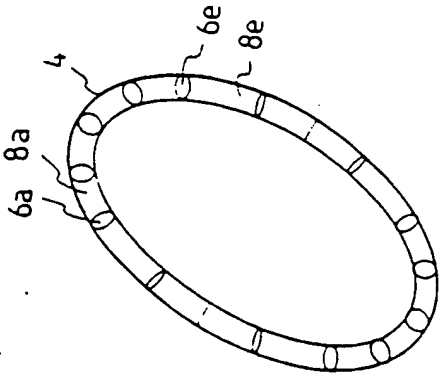

Fig. 2

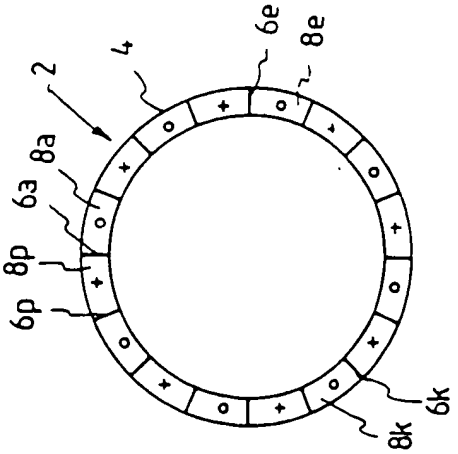

Fig. 1

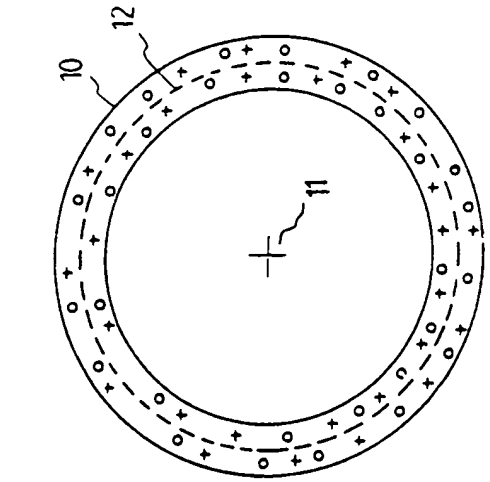

Fig.6

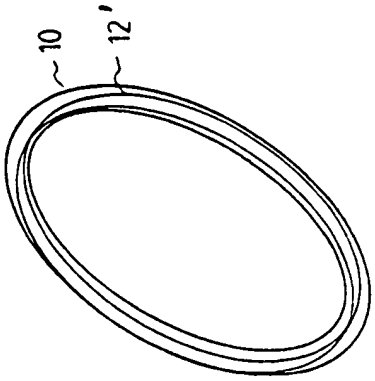

Fig.5

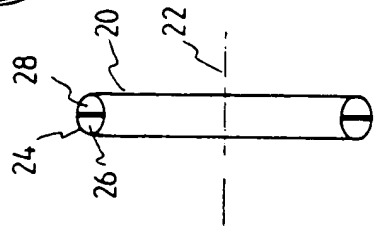

Fig.7

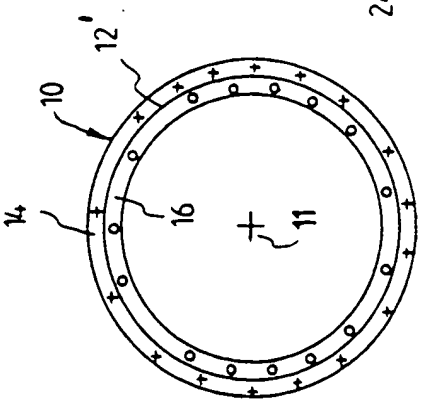

Fig.4

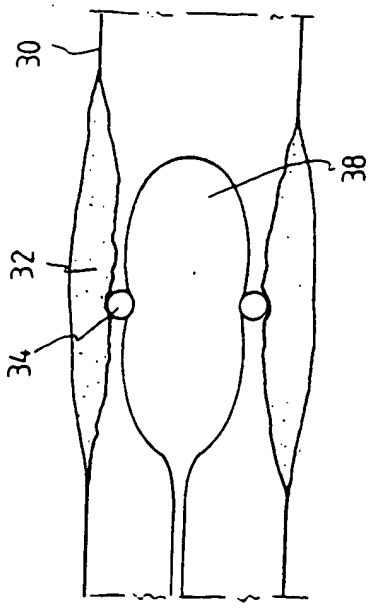

Fig. 9

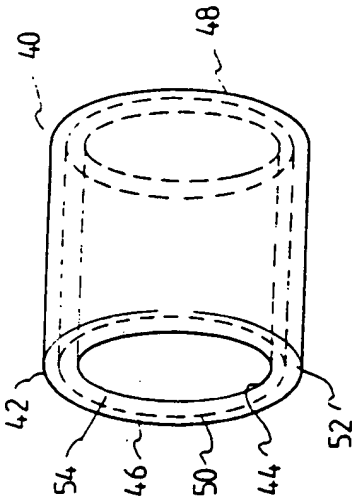

Fig. 11

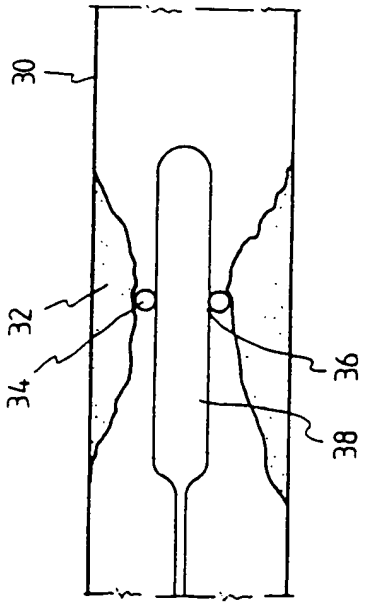

Fig. 8

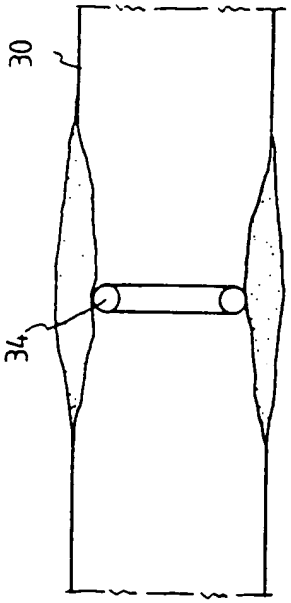

Fig. 10

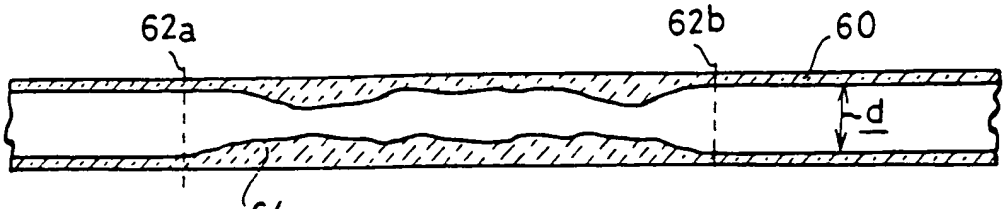

Fig: 12a.

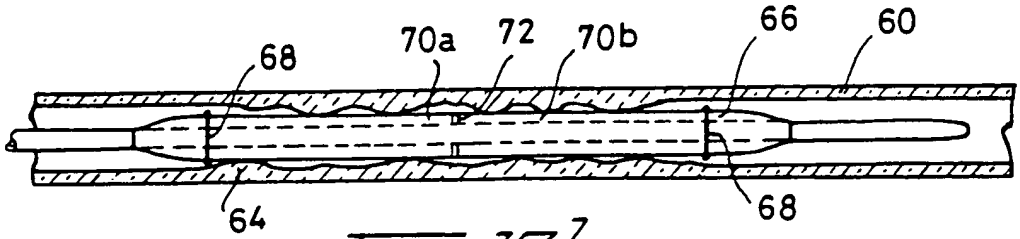

Fig: 12b.

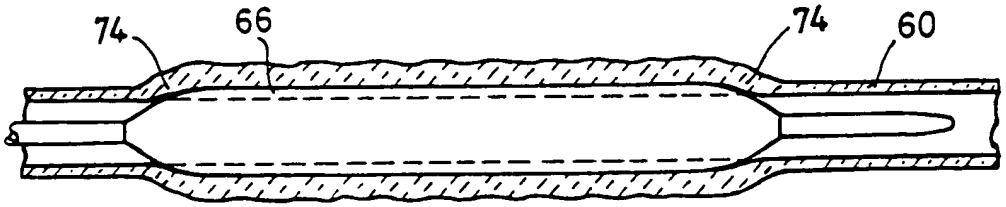

Fig: 12c.

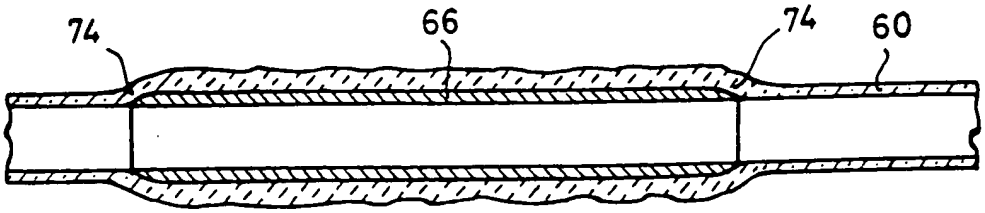

Fig: 12d.

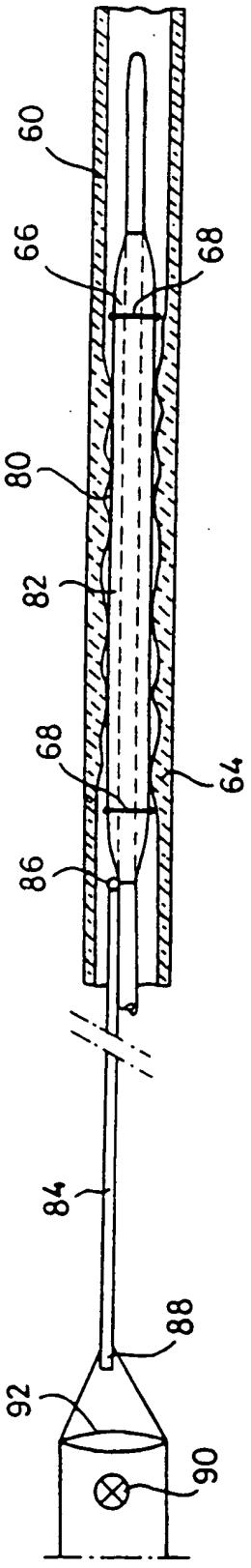

FIG. 13.